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10/763,314	01/22/2004	Michael D. Ries	MLI-10	6544
<div>7590</div> <div>Daniel F. Justin 180 South 600 West Logan, UT 84321</div>				
			<div>EXAMINER</div> <div>SNOW, BRUCE EDWARD</div>	
			<div>ART UNIT</div> <div>3738</div>	<div>PAPER NUMBER</div>
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/763,314  
Filing Date: January 22, 2004  
Appellant(s): RIES ET AL.

**MAILED  
DEC 10 2007  
GROUP 3700**

\_\_\_\_\_  
David Meibos  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 8/20/07 appealing from the Office action mailed 9/29/06.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

6,514,288	Meulink et al	2-2003
6,179,877	Burke	1-2001

EP 5539036

Hoffman et al

4-1993

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-10, 12-18, 20, 42, 43, 45-49, 51-53, 55-53, 55-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

MPEP 714.02 states, "applicant should also specifically point out the support for any amendments made to the disclosure. See **MPEP § 2163.06**." Please in any additional response point out the support for all claim amendments.

Claim 1, "shaped to flex such that, during a normal gait cycle,.." is not found in the original disclosure.

Claim 42, ".. do not differ by more than ten percent.." appears to be new matter.

Claims 43-57 are new matter. Please direct to the specification for support. Unless the specification states the drawings as drawn to scale, applicant cannot use them to support detailed limitations such as ".. do not differ by more than ten percent".

Claims 40-42, 45-57 are rejected under 35 U.S.C. 102(e) as being anticipated by Meulink et al (6,514,288).

Meulink et al teaches a prosthesis adapted for implantation against a resected surface on a proximal end of a femur and inside of an intramedullary cavity of the femur comprising:

- a femoral head component having an external bearing surface and a female friction fit portion (not shown, inherent);

- a femoral stem component comprising:

  - a neck portion 22 having a proximal male friction fit portion, reversibly engagable with the female friction fit portion, and a distal neck body;

  - a flange portion 24 distal and adjacent to the neck portion, attached to the distal neck body, having an upper portion and a bottom surface;

  - a transitional body region, adjacent to the bottom surface of the flange portion and extending from the distal neck body;

  - an elongated stem portion 36 extending distally from the transitional body region and having a longitudinal axis that is orientated at an acute angle from the bottom surface of the flange portion; and

  - a distal end tip portion 50 adjacent and distal to the elongated stem portion;

wherein the transitional body region has a maximum height of less than thirteen millimeters when measured normal from the bottom surface of the flange to any part of the elongated stem portion.

Claims 40-42, 45-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Burke (6,179,877).

Burke teaches a prosthesis adapted for implantation against a resected surface on a proximal end of a femur and inside of an intramedullary cavity of the femur comprising:

- a femoral head component 12 having an external bearing surface and a female friction fit portion;

- a femoral stem component comprising:

- a neck portion having a proximal male friction fit portion, reversibly engagable with the female friction fit portion, and a distal neck body;

- a flange portion 18 distal and adjacent to the neck portion, attached to the distal neck body, having an upper portion and a bottom surface;

- a transitional body region, adjacent to the bottom surface of the flange portion and extending from the distal neck body;

- an elongated stem portion 14 extending distally from the transitional body region and having a longitudinal axis that is orientated at an acute angle from the bottom surface of the flange portion; and

- a distal end tip portion adjacent and distal to the elongated stem portion;

- wherein the transitional body region has a maximum height of less than thirteen millimeters when measured normal from the bottom surface of the flange to any part of the elongated stem portion.

Regarding the boss, see elements 22, 34, 36, 30.

Claims 40-42, 45-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoffman et al (EP 0539036).

Hofmann et al teaches a prosthesis adapted for implantation against a resected surface on a proximal end of a femur and inside of an intramedullary cavity of the femur comprising:

- a femoral head 20 component having an external bearing surface and a female friction fit portion;

- a femoral stem component comprising:

- a neck portion 11 having a proximal male friction fit portion, reversibly engagable with the female friction fit portion, and a distal neck body;

- a flange portion 12 distal and adjacent to the neck portion, attached to the distal neck body, having an upper portion and a bottom surface;

- a transitional body region, adjacent to the bottom surface of the flange portion and extending from the distal neck body;

- an elongated stem portion 25 extending distally from the transitional body region and having a longitudinal axis that is orientated at an acute angle from the bottom surface of the flange portion; and

- a distal end tip portion adjacent and distal to the elongated stem portion;

- wherein the transitional body region has a maximum height of less than thirteen millimeters when measured normal from the bottom surface of the flange to any part of the elongated stem portion.

See flutes 18.

**(10) Response to Argument**

**Claims 1-10, 12-18, 20, 42, 43, 45-49, 51-53, 55-53, 55-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.**

Claim 1, "shaped to flex such that, during a normal gait cycle..." is not supported in the original disclosure. Appellant quotes paragraphs 36-37 which states "loaded during clinical use" and "patient gait" but fails to describe or support "normal gait cycle". What is normal to a track athlete is not normal to an elderly individual. Simply put, "clinical use" and "patient gait" does mean "normal".

Applicant further notes that "significant compressive load" is arguable. None of appellant's citations describe or support the term "significant". One having ordinary skill in the art would not conclude that the term "significant" means something to do with Wolffs Law, other physiologic and biochemical principles, and the stimulation of bone cells.

Claim 42, the wherein clause is new matter which reads: "*wherein, distally of a medial tip of the flange, **any two maximum cross sectional widths** of the elongated stem portion, measured perpendicular to the longitudinal axis, do not differ by more than ten percent.*" The original claim language was "*wherein the elongated stem portion does not vary in its maximum cross sectional width by more than ten percent.*" It is the Examiners position that "*any two maximum cross sectional widths*" only compares maximum cross sectional widths and conveniently fails to include the minimum widths and everything in between in the comparison as required by "*wherein the elongated*



*stem portion does not vary in its maximum cross sectional width by more than ten percent."*

Claim 43, at least "minimum displacement" is not supported.

Claim 44, the rejection is withdrawn.

Claim 45, "radially" is not found in combination with the terms "substantially symmetrical".

Claims 46, for example, the specification teaches "substantially triangle shape" not the claimed "triangle shape".

Claim 47 is not supported by the specification or drawings. The elected embodiment of figures 1-3 teaches a distal section with a circular cross-section. Circular is broader than just a circle.

Claim 48, appellant failed to find support in the specification, additionally, the drawings are not to scale, applicant cannot use them to support detailed limitations such as ".. do not differ by more than ten percent".

Claim 49, see arguments for claim 42 above.

Claim 50, the rejection is withdrawn.

Claim 51, appellant failed to find support in the specification, additionally, the drawings are not drawn to scale, applicant cannot use them to support detailed limitations such as ".. do not differ by more than ten percent".

Claim 52, see arguments for claim 47 above.

Claim 53, see arguments for claim 42 above.

Claim 54, the rejection is withdrawn.

Claim 55, see arguments for claim 42 above.

Claim 56, see arguments for claim 47 above.

Claim 57, see arguments for claim 44 above.

**Claims 40-42, 45-57 are rejected under 35 U.S.C. 102(e) as being anticipated by Meulink et al (6,514,288).**

Regarding claims 40, 45, 50, appellant notes Meulink's teaching of radial symmetry in figures 8 and 9. It is the Examiner's position that at least the noted portion is considered "along substantially the entire length". Appellant arguments are also not commensurate with the scope of the claims; the claim reads, "substantially radially symmetrical". The prosthesis clearly meets this broad limitation of "*wherein, distally of a medial tip of the flange, each cross sectional shape along **substantially** an entire length of the elongated stem portion is **substantially** radially symmetrical.*"

Claims 41, 51, 54. Claim 41 reads, "wherein, distally of a medial tip of the flange, substantially an entire length of the elongated stem portion is circumscribed by a substantially cylindrical shape". The stem of Meulink et al easily meets this broad and unpatentable limitation. It is the Examiner's position that any shape can be circumscribed by a substantially cylindrical shape.

Claims 42, 55, 57. Claim 42 reads, "wherein, distally of a medial tip of the flange, any two maximum cross sectional widths of the elongated stem portion, measured perpendicular to the longitudinal axis, do not differ by more than ten percent." Clearly any two **adjacent** cross sectional widths which meet the claim limitation.

Claim 46, at least figure 8 of Meulink et al showing stem including elements 20, 40, 26, 28 as a circular cross section.

Claim 47, see at least figure 8 showing stem 20 having protrusion 40 which makes it non-circular.

Claims 48-56, see the above arguments.

**Claims 40-42, 45-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Burke (6,179,877).**

Regarding claims 40, 45, 46, and 50. The prosthesis clearly meets this broad limitation of "*wherein, distally of a medial tip of the flange, each cross sectional shape along **substantially** an entire length of the elongated stem portion is **substantially** radially symmetrical.*" See at least figure 6 showing the stem 14 having a rectangular cross section which is substantially radially symmetrical. Radially symmetrical is generally being symmetrical about two planes.

Claims 41, 51, 54. Claim 41 reads, "wherein, distally of a medial tip of the flange, substantially an entire length of the elongated stem portion is circumscribed by a substantially cylindrical shape". The stem of Burke easily meets this broad and unpatentable limitation. It is the Examiner's position that any shape can be circumscribed by a substantially cylindrical shape.

Claims 42, 55, 57. Claim 42 reads, "wherein, distally of a medial tip of the flange, any two maximum cross sectional widths of the elongated stem portion, measured

perpendicular to the longitudinal axis, do not differ by more than ten percent.” Clearly any two **adjacent** cross sectional widths which meet the claim limitation.

Claim 47, the cross section of the stem is generally rectangular which is non-circular but can be considered a “substantially circular shape”.

Claims 48-56, see the above arguments.

**Claims 40-42, 45-57 are rejected under 35 U.S.C. 102(e) as being anticipated by Hoffman (EP 0539036).**

Regarding claims 40, 45, 50. The prosthesis clearly meets the limitation of “*wherein, distally of a medial tip of the flange, each cross sectional shape along **substantially** an entire length of the elongated stem portion is **substantially** radially symmetrical.*” See figure 2, lower portion 25.

Claims 41, 51, 54. Claim 41 reads, “wherein, distally of a medial tip of the flange, substantially an entire length of the elongated stem portion is circumscribed by a substantially cylindrical shape”. See at least lower portion 25; the stem of Hoffman easily meets this broad and unpatentable limitation. It is the Examiner’s position that any shape can be circumscribed by a substantially cylindrical shape.

Claims 42, 55, 57. Claim 42 reads, “wherein, distally of a medial tip of the flange, any two maximum cross sectional widths of the elongated stem portion, measured perpendicular to the longitudinal axis, do not differ by more than ten percent.” Clearly any two **adjacent** cross sectional widths which meet the claim limitation.

Regarding claim 46, a substantially length of the stem portion 25 is considered a circle or star.

Claim 47, the proximal cross section (about mid-stem) is considered substantially circular and the distal section with flutes is non-circular.

Claims 48-56, see the above arguments.

The same reasoning applies to the rejections in view of Burke and Hoffman.

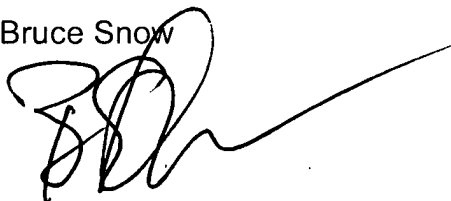
**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

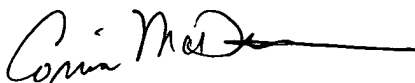
Bruce Snow



**BRUCE SNOW  
PRIMARY EXAMINER**

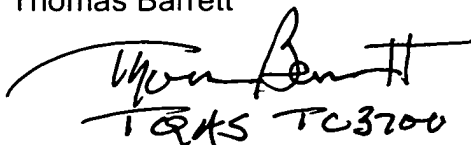
Conferees:

Corrine McDermott



**CORRINE McDERMOTT  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700**

Thomas Barrett



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